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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,481	01/30/2007	Osamu Mori	4600-0116PUS1	8293
2292 7590 06/11/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER WILLIAMS, LELA	
			ART UNIT 1787	PAPER NUMBER
			NOTIFICATION DATE 06/11/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,481	<b>Applicant(s)</b> MORI ET AL.	
	<b>Examiner</b> LELA S. WILLIAMS	<b>Art Unit</b> 1787	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/2010</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. Applicant's amendment filed March 8, 2010 has been fully considered, however the amendment necessitated the new grounds of rejection set forth below. Therefore, the following action is made final.

#### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien.**

**Regarding claims 4 and 11;** Table 1 (page 5) prepares menhaden/corn oil blends in ratios of 10:90, 25:75, 50:50, and 75:25. It is noted that the calculations, of the acids fall out of the presently claimed ranges.

Calculating using the 10:90 ratio, oleic acid (C18:1) is approx. 9.75 parts by weight, linoleic acid (C18:2) is approx. 21.86 parts by weight, and linolenic acid (C18:3) is approx 0.5 parts by weight per one part by weight of long chain highly unsaturated fatty acids (EPA/DHA). Menhaden oil composition is taken to comprise approx. 11.4% C18:1, 1.5% C18:2, 1.6% C18:3, and 24.6 % of EPA/DHA and corn oil composition is taken to comprise approx. 25.4% C18:1, 59.6% C18:2, and 1.2% C18:3, as shown by O'Brien.

However, given that the amounts of the acids would vary due to the ratios and the present application does not show the amounts to be critical, the desired amounts of the acids are considered an results effective amount and the determination of a workable amount would have

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been within the ambit of one of ordinary skill in the art without undue experimentation. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980) (see MPEP § 2144.05, II.). Therefore it would have been obvious to one of ordinary skill in the art to choose amounts of oleic, linoleic, and linolenic acids, including the amounts presently claimed, in order to produce final product with desired properties.

**Regarding claim 6**, the ratio of the EPA and/or DHA in the composition is approx. 3% of the whole fatty acid composition. The “whole fatty acid composition” is taken to comprise oleic, linoleic, linolenic, and EPA/DHA.

**Regarding claim 7**, the long chain highly unsaturated fatty acids are EPA or DHA (Table 1).

**Regarding claim 8**, the blend disclosed by Freeman et al. does not contain any added antioxidants.

**Regarding claims 10 and 11**, given that it would have been obvious to one of ordinary skill in the art to use amounts of oleic acid, linoleic acid, and linolenic acid as presently claimed and as discussed above with respect to claim 4, it is clear that the resulting fat or oil would intrinsically be a liquid at 5°C.

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**3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien and in view of Motoharu et al. JP 11-299420.**

**Regarding claim 9**, Freeman et al. discloses adding antioxidants by teaching that TBHQ is known to be a more effective antioxidant in the stabilization of fish oil. Freeman is silent on the amount to use. Motoharu discloses the use of antioxidants in a fat and oil composition, and discloses 0.001-0.2% of ascorbic acids (L-ascorbic acid) is an effective amount [0006]. Given that Motoharu discloses the presently claimed amount of antioxidant being sufficient for use in an oil and fat composition, one of ordinary skill would find it obvious to incorporate said amount to improve the oxidation stability and flavor of DHA [0018].

***Response to Amendment***

4. Claims 4 and 6-11 are currently pending. Claims 1-3 and 5 are cancelled.

5. Applicant's amendment filed March 8, 2010 is sufficient to overcome the 35 U.S.C §102(b), rejections of the previous office action. Therefore the rejection has been withdrawn.

***Response to Arguments***

Applicant's arguments, filed March 8, 2010, with respect to the rejection(s) of claim(s) 4, 6-8 and 10-11 under 35 U.S.C §102(b) as being anticipated by Freeman et al (EP 0304115) as further explained by O'Brien, has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien.

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As stated above, it is noted that the ranges of the acids in Freeman fall outside of the presently claimed ranges, however, given that the amounts of the acids would vary due to the ratios and the present application does not show the amounts to be critical, the desired amounts of the acids are considered an results effective amount and the determination of a workable amount would have been within the ambit of one of ordinary skill in the art without undue experimentation. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980) (see MPEP § 2144.05, II.). Therefore it would have been obvious to one of ordinary skill in the art to choose amounts of oleic, linoleic, and linolenic acids, including the amounts presently claimed, in order to produce final product with desired properties.

Applicant’s argument of unexpected results has been noted, however are not persuasive. Applicant points to Table 6 of the present specification to demonstrate Examples A and B "superior result", however Examples 1,2 and C, which all show the use of lower amounts of oleic, linoleic, and linolenic acids also provides sufficient results. These said results render it obvious that the amounts of the acids are result effective variables and the determination of a workable amount would have been within the ambit of one of ordinary skill in the art without undue experimentation.

Further the data is not commensurate in scope with the scope of the closest prior art, O'Brien, given that the values disclosed by O'Brien, i.e. 9,75 parts oleic acid, 21.86 parts linoleic

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acid, and 0.5 parts linolenic acid, are closer to the presently claimed values, than those set forth in the comparative examples. Further, the data is not persuasive given that the properties appear to depend on the storage days and at 0 days all the examples including the comparative examples are tasteless and odorless. Further, examples A-C are tasteless and odorless for 4 days. This is especially significant given that there is no requirement in the claims regarding storage days.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LELA S. WILLIAMS/  
Examiner, Art Unit 1787

/L. S. W. /

/Callie E. Shosho/  
Supervisory Patent Examiner, Art Unit 1787